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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,797	04/21/2004	Herbert M. Dean	dean0404con	5067

23580 7590 01/06/2006

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,797	DEAN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed 14 September 2005 has been received and entered. Claims 5 and 7 has/have been amended. Claims 1-14 are pending to which the following grounds of rejection are or remain applicable.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. U.S. Patent No. 6,140,319 A.

Claims 1-7 and 14 are drawn to a medicament dosage unit consisting essentially of a beta-adrenergic blocker and a platelet inhibitor in a single unit. Dependent claims are drawn to aspirin as the platelet inhibitor and atenolol, propranolol, timolol and metoprolol as the beta-blockers. Claims 8-11 are drawn to a method of treating cardiovascular disease comprising administering a single dosage unit consisting essentially of a beta-adrenergic blocker and a platelet inhibitor. Claims 12-13 are drawn to a method for making a cardiovascular protective dosage unit, which consists essentially of formulating a single dosage unit consisting essentially of a beta-adrenergic blocker and a platelet inhibitor.

Powell et al. teach a single dosage unit of a vasopeptidase inhibitor combined with a beta-blocker and an antiplatelet agent (column 2, lines 5-13). It differs in that it includes a vasopeptidase inhibitor. The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52. For the purposes of searching for and applying prior art under35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are,

"consisting essentially of" will be construed as equivalent to "comprising." If the applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USP 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). It does not appear that the addition of a vasopeptidase inhibitor would materially change the characteristics of the applicant's invention, since a vasopeptidase inhibitor would also treat cardiovascular disease. Since there is no detail regarding the method of making a medicament, it reads on the "single dosage form" of the prior art. Powell et al. teach the compositions useful for cardiovascular disorders such as angina pectoris (column 1, line 66 to column 2, line 1). Beta-blockers for the invention include agents such as propranolol, timolol, metoprolol and atenolol and antiplatelet agents such as aspirin (column 4, lines 6-28).

Response to Amendment

Objection to claims 5 and 7 is no longer maintained and hereby withdrawn in view of the amendment.

Response to Arguments

Applicant's arguments filed 14 September 2005 have been fully considered but they are not persuasive. The rejection made in the paper mailed 29 June 2005 under 35

U.S.C. §103(a) over Powell et al. is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

Applicant asserts that the examiner's interpretation of the transitional phrase "consisting essentially of" is arbitrary and contrary to established law. The examiner is not in agreement and if the applicant's representative would like to consult the MPEP, the interpretation can be found in MPEP §2111.03 [R-3].

Applicant argues that the vasopeptidase inhibitor that is taught by Powell et al in combination with a beta-blocking agent would result in a dosage unit that inherently has added risk for an individual with cardiovascular disease. Applicant has included some exhibits detailing the deleterious effects of said vasopeptidase inhibitors. In response, one can find side effects and warnings attached to every medicament on the market, including beta blockers that cause *mortality* according to the National Heart Lung and Blood Institute when they conducted the Cardiac Arrhythmia Suppression Trial (CAST), plus a whole host of other maladies that are detailed in the enclosed pages of Drug Facts and Comparisons (1994). Aspirin and other platelet aggregation inhibitors also carry a host of warnings, including erosion of stomach lining and bronchospasm, generalized urticaria/angioedema (similar to the vasopeptidase inhibitors exhibits). See Drug Facts and Comparisons (1994) enclosed. The prior art listed above as Drug Facts and Comparisons (1994), pertinent to applicant's disclosure, is made of record and not relied upon.

Since the prior art combination of vasopeptidase inhibitor combined with aspirin and beta adrenergic blockers has the same utility (treatment of cardiovascular

disorders) it would have been made obvious to one of ordinary skill in art at the time it was made to combine a beta-adrenergic blocker with aspirin in a single dosage unit motivated by the teachings of Powell such agents are effective for treatment of cardiovascular disorders. One skilled in the art would have been motivated to prepare additional useful compositions. In the absence of any criticality and/or unexpected results of the combination of a beta-blocker and platelet aggregation inhibitor, the instant invention is considered obvious.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

12/21/2005

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